510(k) Summary
(*per 21 CFR 807.92*)
Boston Keratoprosthesis

MAY 10 2013

1. SPONSOR

Massachusetts Eye & Ear Infirmary, d/b/a Boston Keratoprosthesis
243 Charles Street
Boston, MA 02114

Contact Person: Larisa Gelfand
Position: Manager of Boston Keratoprosthesis Program
Telephone: 617-573-4463

2. CONSULTANT/CONTACT

Aptiv Solutions
43 Plain Street
North Attleboro, MA 02760

Primary Contact: Brian J. Edwards
Position: Senior Regulatory Staff Consultant
Telephone: 651-542-1413

3. DEVICE NAME

Proprietary Name:	Boston Keratoprosthesis, Type I or Type II
Common/Usual Name:	Keratoprosthesis
Classification Name:	Keratoprosthesis, Permanent Implant
Product Code:	HQM
Regulation Number:	21 CFR 886.3400

4. PREDICATE DEVICES

- Massachusetts Eye & Ear Infirmary's Keratoprosthesis previously cleared on January 21, 1992 under Premarket Notification Number K915062.

5. DEVICE DESCRIPTION

The Boston Keratoprosthesis is an artificial corneal device that can be used in patients with severe corneal opacity.

The Boston Keratoprosthesis is used after standard corneal transplant has failed or when such a transplant would be unlikely to succeed. Thus, keratoprosthesis implantation is a procedure designed to help patients whose conditions are the most difficult to treat.

This 510(k) seeks to modify the back plate material from PMMA to titanium. In doing so, the modified implant eliminates the need for a titanium retaining ring which was employed in the predecessors to hold the PMMA back plate in position following implantation. This also simplifies the assembly.

It is available in two types. The Type I keratoprosthesis is implanted through and fixed only to the cornea and is used for corneal blindness when the eyelids, blink mechanism and tear film are intact. The Type II keratoprosthesis has an anterior extension to enable implantation through an opening in the closed eyelids. The Type II device is used in eyes with severe dry eye, mucosal keratinization and obliteration of the normal conjunctival fornices, such as after severe chemical injuries or Stevens Johnson syndrome or mucous membrane pemphigoid.

Both devices are identical in terms of assembly.

6. INTENDED USE

The Boston Keratoprosthesis is indicated to provide a transparent optical pathway through an opacified cornea in an eye that is not a reasonable candidate for any form of corneal transplant, including penetrating keratoplasty.

7. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The subject of this 510(k) is a modification of the Boston Keratoprosthesis that was previously cleared on January 21, 1992 under Premarket Notification Number K915062. The subject of this 510(k) is the change in material of the back plate from the original poly(methyl methacrylate) (PMMA) to titanium, with elimination of the necessity for the titanium locking ring. The new titanium back plate combines back plate and locking ring functions.

8. PERFORMANCE TESTING

Validation activities to support the use of the Boston Keratoprosthesis device consisted of the following elements:

- Sterility Validation
- Bioburden
- LAL
- MRI Compatibility
- Shelf Life Testing

Testing of the Boston Keratoprosthesis has demonstrated that the material change from PMMA to titanium does not modify product performance and the product fulfills prospectively defined performance criteria and that the modified system meets user needs.

9. CLINICAL TESTING

The clinical performance data included 86 eyes in 86 subjects implanted with the modified titanium back plate device and 55 eyes in 50 subjects with the predicate polymethyl methacrylate (PMMA) device. For implanted eyes, mean follow-up was 14.8 months with a maximum follow-up of 38 months.

The clinical data shows that the titanium back plate is as safe and effective as the predicate PMMA back plate for use in the Boston Keratoprosthesis.

10. Conclusions Drawn from Non-Clinical and Clinical Tests

The Boston Keratoprosthesis with titanium back plate has the same intended use and similar technological characteristics as the Boston Keratoprosthesis with PMMA back plate predicate device. Non-clinical testing demonstrates that the titanium version is biocompatible and possesses similar assembly strength profiles to the PMMA version.

All the data collected confirms that the differences in the design of the Boston Keratoprosthesis with titanium back plate does not raise any new issues of safety and effectiveness when compared to the predicate design with a PMMA back plate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 10, 2013

Massachusetts Eye & Ear Infirmary
% Mr. Brian J. Edwards
Senior Regulatory Staff Consultant
62 Forest Street, Suite 300
Marlborough, MA 01752

Re: K121203
Trade/Device Name: Boston Keratoprosthesis, Type I and Type II
Regulation Number: 21 CFR 886.3400
Regulation Name: Keratoprosthesis
Regulatory Class: Class II
Product Code: HQM
Dated: April 25, 2013
Received: April 26, 2013

Dear Mr. Edwards:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): 121203

Device Name: Boston Keratoprosthesis

Indications for Use:

The Boston Keratoprosthesis is indicated to provide a transparent optical pathway through an opacified cornea in an eye that is not a reasonable candidate for any form of corneal transplant, including penetrating keratoplasty.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use ____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Tieuvi H Nguyen -S
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(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices
510(k) Number: K121203